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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,402	02/15/2001	Pericles Calias	5007	2991

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GENZYME CORPORATION
LEGAL DEPARTMENT
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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 11/14/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

29/78442

Applicant(s)

Calias et al

Examiner

Kraft

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/28/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-54 is/are pending in the application.
- Of the above claim(s) 1-28 + 45-54 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 29-44 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11 filed 8/28/02
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

In a response of 8/28/02 to a restriction requirement of 6/28/02, applicants elected Group III claims 29-44 without traverse.

Claims 1-28 and 45-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9 of 8/28/02.

The drawings filed 8/26/02 have been approved by the draftsman.

Claims examined on the merits are 29-44.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-36 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is not clear antecedent basis for "the organic compound" in claims 33, 34, 41 and 42, and for "the terminal group" in claims 35, 36, 43 and 44. Claims 29 and 37 require an "organic disulfide compound" and a "terminal portion". To be clear, the dependent claims should be consistent with the independent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes 10 that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the 15 examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pouyani et al (9) in view of Latham et al (17), Zara et al (5,157,123), Prestwich et al (5,874,417) and Bernkop-Schnurch et al 20 (26).

The claims require a chemically modified biopolymer that is the reaction product of a biopolymer containing a carboxyl group, an activating agent, and an organic disulfide compound containing an amino or hydroxyl group.

25 Pouyani et al disclose producing derivatives of hyaluronic acid for use as a drug carrier by coupling a linker to the hyaluronic acid and then attaching a drug to the linker (Fig 2).

Latham et al disclose using a disulfide linkage between an oligonucleotide and a transport agent such as cellulose (page 18, lines 30 3-5 and page 23, line 6).

Zara et al disclose coupling a crosslinker containing a disulfide linkage to a biomolecule (col 5, lines 3-14 and col 7, lines 25-55).

Prestwich et al disclose derivatizing hyaluronic acid with crosslinkers containing a disulfide linkage (Figs 5H and 5R, and scheme 2(2b) and scheme 3(2e)).

Bernkop-Schnurch et al disclose a thiolated polymer produced by reacting a carboxyl group of the polymer with the amino group of cysteine in the presence of a carbodiimide (Fig 1).

It would have been obvious to use as the linker of Pouyani et al a linker or crosslinker containing a disulfide linkage as taught by Latham et al, Zara et al and Prestwich et al to obtain the function of the disulfide linkage, and it would have been obvious to couple an amino group of the linker or crosslinker to a carboxyl group of the hyaluronic acid using a carbodiimide as taught by Bernkop-Schnurch et al since this coupling reaction would have been expected to be an efficient and effective way to carry out coupling. Selecting biopolymers other than hyaluronic acid would have been a matter of individual preference since it would have been expected that any biopolymer having the appropriate reactive group could be used.

Claims 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pouyani et al in view of Latham et al, Zara et al, Prestwich et al and Margel et al (5,855,987).

The claims require a chemically modified biopolymer that is the reaction product of a biopolymer containing a carbonyl group, a reducing

agent, and an organic disulfide compound containing an amino or hydroxyl group.

Pouyani et al, Latham et al, Zara et al and Prestwich et al are described above.

5 Margel et al disclose (Figs 1 and 2, and col 1, lines 15-22) coupling amino compounds to cellulose by reacting an aldehyde group of the cellulose with an amino group of the compound to form a schiff base bond and reducing the schiff base bond with a reducing agent.

10 When coupling a disulfide-containing linker or crosslinker to the hyaluronic acid of Pouyani et al as suggested by Latham et al, Zara et al and Prestwich et al as set forth above, it would have been obvious carry out coupling using the method of forming a schiff base bond between amino and aldehyde groups and reducing the bond as disclosed by Margel et al when coupling amino compounds to cellulose since this coupling method
15 would have been expected to be an effective method for coupling the linker or crosslinker to hyaluronic acid. Selecting biopolymers other than hyaluronic acid would have been a matter of individual preference since it would have been expected that any biopolymer having the appropriate reactive group could be used.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

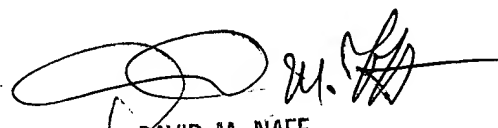
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number

5 (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist

10 whose telephone number is (703) 308-0196.


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 12851

15 DMN
11/8/02